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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/782,874	02/08/2001	Michael Wassenegger	MPG-1 DIV-1	6565
110 7590 01/12/2005 DANN, DORFMAN, HERRELL & SKILLMAN 1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307			EXAMINER HELMER, GEORGIA L	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/782,874

Applicant(s)

WASSENEGGER ET AL.

Examiner

Georgia L. Helmer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-35, 37, 48 and 65-70 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-35, 37, 48 and 65-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

1. The Office acknowledges receipt of Applicant's Amendment After Final filed 21 October 2004.
2. The Finality of the previous Office Action is withdrawn.
3. The Amendment After Final filed 21 October 2004 has been entered. However the claims are not in condition for allowance.
4. Claims 29-35, 37, 48, and 65-70 are pending, and are examined in the instant action.
5. All rejections not addressed below have been withdrawn.
6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Objection

7. The attempt to incorporate subject matter into this application by reference to Amasino, Analytical Biochemistry, 1986, Vol 152, pages 304-307, is improper because the subject matter provides essential information of the claimed invention. Applicant should amend the specification to specifically recite the essential subject matter, namely the specific hybridization conditions found on p. 304 last 7 lines of ¶ bridging p. 305 and the wash conditions found on p. 305 lines 2-8, of the reference.

Claim Rejections - 35 USC § 112-1 - Written Description

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8. Claims 29-35, 37, 48, 64-70 and 72-74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for reasons of record.

Claim 29 is drawn to a plant cell comprising a foreign nucleic acid molecule ...wherein the nucleic acid molecule is one encoding a polypeptide having the enzymatic activity of an RdRP or encoding an "enzymatically active fragment" thereof ..., that specifically hybridizes to a complementary strand of a nucleic acid molecules..in " 0.25 M NaHPO₄ pH 7.2, 0.25 M NaCl, 7% SDS, 1 mM EDTA and 5-20 %polyethylene glycol at 42 degrees C for 4-24 hours" .

The claims are drawn to sequences that encode an "enzymatically active fragment" of the RdRP. However, the specification does not disclose what structural features would be conserved in the claimed sequences that would result in the claimed enzyme activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

The claims are also a transgenic plant cell comprising a foreign nucleic acid stably integrated into the genome, wherein the nucleic acid molecule is a nucleic acid molecule coding an RNA molecule that is capable of serving as a template for RNA directed RNA synthesis, wherein the template nucleic acid is linked to appropriate regulatory elements. However, the specification does not disclose what structural features would be conserved in the claimed sequences that would result in the claimed

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enzyme activity. Applicants are claiming a genus of sequences, yet there is no description of the structural features that define the genus.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA Accordingly, the specification does not provide a written description of the invention"

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

Claim Rejections - 35 USC § 112-Enablement

9. Claims 29-35, 37, 48, 64-70 and 72-74 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims to a nucleic acid of SEQ ID NO: 1 or a nucleic acid encoding SEQ ID NO: 2, which has RdRP enzymatic activity, does not reasonably provide enablement for any sequences wherein the nucleic acid molecule is one encoding a polypeptide having the enzymatic activity of an RdRP or encoding an "enzymatically active fragment" thereof ..., that specifically hybridizes to a complementary strand of a nucleic acid molecules..in " 0.25 M NaHPO4 pH 7.2, 0.25 M NaCl, 7% SDS, 1 mM EDTA and 5-20 %polyethylene glycol at 42 degrees C for 4-24 hours".

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Applicant claims an "enzymatically active fragment" of the RdRP. Applicant teaches SEQ ID NO: 2, the complete coding sequence. Applicant gives not guidance for the size of the fragment, which can range from 1 amino acid to 1112 amino acids. and which can consist on any and all oligomers of 2-mers to 1112-mers beginning at the N-terminal end and continuing through to the C-terminal end of SEQ ID NO: 2.

Furthermore, Applicant claims the nucleic acid molecule encoding a polypeptide having the enzymatic activity of an RdRP or encoding an "enzymatically active fragment" thereof ..., that specifically hybridizes to a complementary strand of a nucleic acid molecules..in " 0.25 M NaHPO₄ pH 7.2, 0.25 M NaCl, 7% SDS, 1 mM EDTA and 5-20 %polyethylene glycol at 42 degrees C for 4-24 hours".

The hybridization conditions given are of very low stringency, and would select little if any specific sequences. This because the hybridization stringency is a function of both temperature and salt concentration. The 42 degrees C condition is a low temperature, which would allow much non-specific binding of nucleic acid sequences. And furthermore, the salts conditions are such that nonselective sequence binding would be very frequent, causing sequences which are so selected to have a high degree of randomness (Maniatis, 1982, pages 388-389).

The hybridization conditions given in the text of Claim 29 are miscopied from the original reference, Amasino, 1985, page 304. The terms "50% formamide" was omitted in the copying, making the conditions given in the claims inoperable in the claimed invention.

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The wash conditions for the hybridization also determine the stringency, the more stringent the wash conditions, the more chance of selecting specific sequences.

However, no wash conditions are given in the claims. The wash conditions given in Amasino, page 305, need to be properly incorporated by reference, and then copied verbatim into the claims.


Remarks

10. No claim is allowed.
11. SEQ ID NO: 1 and 2 are free of the prior art of record.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 571-272-0796. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Georgia L. Helmer PhD
Patent Examiner
Art Unit 1638
December 30, 2004


ELIZABETH MCELWAIN
PRIMARY EXAMINER